| Title: DIVISION INTERNAL QUALITY AUDITS | Number: D65-17-01 | Revision No.: OD | Effective Date: 31 JAN 97 |
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| | Prepared By: Thomas J. Underwood | Approved By: Thomas S. Dodson | Page: 1 OF 2 |

31 January 1997

STANDARD OPERATING PROCEDURE D65-17-01

From: D65
To: D65 Division

Subj: DIVISION INTERNAL QUALITY AUDITS

Ref: (a) SOP D65-14-01, Division Corrective and Preventive Actions

Encl: (1) Corrective Action Request Form

1. Purpose. To establish a system and provide instructions for conducting internal quality audits.

2. Scope and Application. This procedure applies to all Division staff functions and Branches responsible for compliance with established Quality procedures.

3. Policy. All Division Branches and staff functions will be subject to internal audits for compliance with established procedures.

4. Procedure. This procedure identifies audit planning responsibility and frequency of audits, composition of the Audit Team, preparation for and conducting the Audits, corrective action and follow-up, and documenting/recording Audit results.

a. Planning - The Quality Assurance (QA) Manager is responsible for planning and scheduling the internal audits. Each Branch and Division staff function will be audited at least twice a year. In addition to the bi-annually scheduled audits, the QA Manager may select certain functions for more frequent auditing, depending on their status and past compliance history. The audit plan will address all procedures and processes corresponding to the 20 sections of the Division Quality Manual, locations of Division Branches and staff functions subject to auditing, and an audit date for each Branch and/or function.

b. Audit Team. Each Branch will have a designated auditor trained in ISO 9001 auditing techniques and requirements. Personnel assigned to carry out internal audits are independent of those having direct responsibility for the audited activity. The QA Manager, assisted by a trained inspector, will lead/chair the Audit Team. Personnel from other departments trained in ISO 9001 auditing techniques may assist Division Audit Teams, but only in an advisory capacity. Activities that are the responsibility of the QA department will be audited by the Division Head or his designated representative.

c. Auditor Training - External training and/or certification of auditors is not required; however, the QA Manager maintains a library of publications, articles, and standards instructing in auditing techniques, and "auditors-in-training" will require internal training in auditing techniques conducted by QA. This training will be recorded in the person's training records.

d. Preparation for and conducting Internal Audits - The QA Manager will ensure that auditors prepare for an audit by fully familiarizing themselves with the ISO 9001 standard, refreshing their knowledge of the quality manual and relevant operational procedures, reviewing the nonconformity reports and corrective actions files, and preparing questions and checklists. The Branch Head/supervisor responsible for the area being audited will be contacted at least one week in advance with the proposed audit date. The Supervisor is required to confirm the proposed date or propose an alternate date. While conducting the audit, the auditors seek objective evidence demonstrating whether the audited activities comply with the requirements of the documented quality system. When a noncompliance is noted, it is brought to the attention of, and discussed with, the responsible Supervisor. Before the end of an audit day, each noncompliance noted during the day is documented on the Corrective Action Request Form (see Enclosure (1)).

e. Corrective Action and Follow-up - Once a noncompliance is identified and documented, further processing of the Corrective Action Request Form follows the same procedure as applies to corrective action requests (SOP-14-01). Upon receiving the form, the responsible Branch Head/supervisor will investigate the cause of the problem noted as a noncompliance, propose a corrective action to be taken, and indicate the date by which the corrective action will be fully implemented. The auditor reviews and approves the proposed action. NOTE - Major problems or issues may be elevated to the QRB. On, or immediately after, the due date for implementation of the corrective action, the auditor follows up with an inquiry or an audit to determine if the corrective action has been implemented and if it has been effective. When there is objective evidence that the corrective action has been effective, the Corrective Action Request Form is closed out. If the problem or issue still exists, a new Form will be initiated requiring a re-evaluation of the problem by the responsible Branch Head/supervisor.

5. Documentation and Record - Internal audits, implementation of resulting corrective actions, and the follow-up audits are documented using the Corrective Action Request Form. Pending Corrective Action Request Forms will be kept by the auditor that initially issued the report. Storage location and retention period for closed-out of these forms are specified in Procedure SOP-16-01, Quality Records.

THOMAS S. DODSON

**CORRECTIVE ACTION REQUEST FORM**

**TO:** _____ **CC:** _____

**FROM:** _____ **CC:** _____

**RETURN TO:** _____ **CC:** _____

**SUBJECT:** _____ **REPORT NO.:** __

**LOCATION/AREA:** _____ **DATE:** _____

**DISCUSSED WITH:** _____ **AUDITOR:** _____

**DOCUMENT REVIEWED:** _____ _____

**DEF. CATEGORY: CRITICAL MAJOR MINOR**

**SPECIFICATION NUMBER AND STATEMENT OF REQUIREMENT:**

**OBSERVATIONS:**

**RECOMMENDATIONS:**

**ACTION AGREED WITHIN _____ DAYS ACKNOWLEDGMENT_____**

**Enclosure (1)**